JAN 12 2007

K063826

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by 21 CFR part 807.87(h)

1. Submitted By:

Frank Pokrop
Manager, Regulatory Affairs
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Siemens Medical Solutions USA, Inc.
Molecular Imaging Group
2501 N. Barrington Road
Hoffman Estates, IL 60195
Frank.Pokrop@Siemens.com

2. Date Prepared: December 14, 2006

3. Name/Classification of Device:

System, Imaging Processing, Radiological
Class II
Picture Archiving and Communications System
21 CFR Part 892.2050
90 LLZ
Radiology Panel

4. Trade Name of Proposed Device: syngo MI Applications 2007A

5. Predicate Devices:

510(k) #:	Trade Name	Manufacturer
K992731	e.Cam Computer	Siemens Medical Solutions USA, Inc.
K023190	e.Cam Computer/ e.soft Workstation	Siemens Medical Solutions USA, Inc.
K041166	Siemens Enhanced Imaging System (a.k.a., Symbia)	Siemens Medical Solutions USA, Inc.

6. Manufacturer and Distributor:

Siemens Medical Solutions USA, Inc.
Molecular Imaging Group
2501 N. Barrington Road
Hoffman Estates, IL 60195

PROPOSED DEVICE DESCRIPTION

The proposed device is a software-only update intended for use with nuclear medicine applications. The software functions as the primary user interface for acquiring, viewing, manipulating, post-processing and archiving images from the Siemens family of:

- dedicated SPECT and PET systems, and,
- SPECT/CT and PET/CT multi-modality systems

The software collects clinical applications data for digital processing and viewing of images and also provides data and images for later use with third party software applications. Reviewing of images from remote locations is also possible with a limited but mobile version of this program.

The proposed device provides healthcare practitioners the ability to work with Siemens SPECT, PET, CT and other images while using standard networking and image transfer protocols such as DICOM and TCP/IP for connections to and from other devices and imaging stations. Communication capabilities consist of image review and data storage workstations through the use of the PACS protocol. Lastly, the proposed software also works with hardcopy devices, external archive devices and HIS/RIS - or Hospital Information / Radiological Information Systems.

DESCRIPTION OF CHANGES OR MODIFICATIONS

The changes made to the proposed device consist of software and performance refinements including:

(1) More effective processing:
    a. Enhanced planar processing: post processing provides ancillary images based on Pixon® proprietary algorithms. Together with the original images, the Pixon-based images can improve image analysis, allow reduction of dose, allow reduction of acquisition time, or any combination thereof.
    b. Tomographic processing: Flash 3D can improve image analysis, allow reduction of dose, allow reduction of acquisition time, or any combination thereof.
(2) Built-in quality control reminders so the user can maintain camera performance
(3) Remote maintenance and software queries
(4) 64 bit operation
(5) Mobile viewing with syngo MI Mobile applications
(6) Image display using syngo Media Viewer
(7) Functionality with a broad suite of third party software applications

INDICATIONS FOR USE

Syngo MI Applications is a noninvasive software program that is used to acquire, view, manipulate, post-process and archive images from the Siemens gamma cameras, PET instruments and CT systems. It is a medical image and information management system capable of functioning in several distinct methods of operation which are described in this summary.

Syngo MI Applications 2007A is a software product intended for use with nuclear medicine applications. It is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, PET, CT and other imaging modalities.

It is used to detect or image the distribution of radionuclides in the body or organ(s) using the following techniques:

- planar imaging and processing
- whole body imaging and processing
- tomographic imaging and processing
- positron imaging by coincidence
- positron imaging without coincidence up to 588 keV
- display, process and fusion of nuclear medicine, PET, CT and hybrid images.

COMPARISON WITH PREDICATE DEVICES

The proposed device will use technology that is similar to the technology already in use by Siemens Medical Solutions. The proposed device uses the same hardware platforms and the same software language like each of the predicate devices. It also has the same intended use and the same indications for use as the predicate devices. Fundamental concepts and principles of operation also remain the same.

A detailed comparison with the predicate devices is included in Section 11 of the submission. The claim for substantial equivalence is also detailed within this submission.

Syngo MI Applications 2007A as described in this Premarket Notification has the same intended use and similar technical characteristics as the devices listed above and is substantially equivalent to those products.

PRODUCTS COVERED IN THIS SUBMISSION

Testing and validation of the following products are covered by this submission:

	PRODUCT	COMMENT
1	syngo MI Applications 2007A	A fully featured software product covering all imaging functions and modalities
2	Software controlled versions of syngo MI Applications 2007A	Limited and feature-specific versions of the high-level program are dedicated to one of the following activities: Acquisition, Processing, Viewing, Cardiac only
3	syngo MI Mobile	A mobile version of the high-level program intended for remote viewing of images
4	syngo Media Viewer	For copying and viewing images
5	Functionality with Third Party Software	4DMSPECT, Emory, Neurogam, Scenium, Fusion 7D, IDL, Cedars

GENERAL SAFETY AND EFFECTIVENESS CONCERNS

The software is intended to be used by appropriately trained health care professionals. The proposed device contains instructions for use as well as the necessary cautions and warnings to provide for safe and effective use of the device

To identify potential hazards, risk management is ensured through a risk analysis and other tools to appropriately address potential hazards. These potential hazards are controlled via software development, verification and validation testing.

In summary, Siemens believes that the software product, syngo MI Applications 2007A does not introduce any potential safety risks and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Frank Pokrop
Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Molecular Imaging Group
2501 North Barrington Road
HOFFMAN ESTATES IL 60192-2061

JAN 12 2007

Re: K063826
Trade/Device Name: Syngo MI Applications 2007A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 15, 2006
Received: December 26, 2006

Dear Mr. Pokrop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SIEMENS

Indications for Use

510(k) Number (if known): K063826

Device Name: Syngo MI Applications 2007A

Indications for Use:

Syngo MI Applications 2007A is a software product intended for use with nuclear medicine applications. It is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, PET, CT and other imaging modalities.

It is used to detect or image the distribution of radionuclides in the body or organ(s) using the following techniques:

- planar imaging and processing
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- tomographic imaging
- positron imaging by coincidence
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- display, process and fusion of nuclear medicine, SPECT, PET, CT and hybrid images.

Prescription Use ✓ OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063826